

Memo

To: Troy Hershberger  
John Susaraba  
Richard Smith

From: John M. Cuckler, M.D.

Date: June 23, 2003

Subject: recent metal-metal meeting in Montreal



I just returned from the Montreal metal-metal meeting and wanted to bring several issues to your attention which I think will be of significance to the M2a product line. Enclosed are copies of the abstracts of the significant papers.

Of greatest concern to me was the paper by Hans Willert on hypersensitivity around metal-metal hips. A copy of his paper is included. Basically, he found about 66 percent of revision cases (Metasul hips) showed histologic evidence of a lymphocytic vasculitis, which he interprets as an allergic response to the metal particulate and/or metal-protein complexes resulting from wear.

I'm particularly concerned that this data will be used by proponents of other bearing couples, or even worse, malpractice lawyers. Willert's conclusion to his presentation is that patients should be questioned before surgery as to any history of metal sensitivity. He would consider this to be a contraindication to use of metal-metal hip replacement. In addition, he believes that patients with persistent pain after metal-metal hip replacement need to be investigated for the possibility of metal sensitivity. He stated that persistent joint effusion, chronic bursitis, and unexplained pain are consistent with a hypersensitivity reaction to the metal-metal hip. He suggests that revision to a different wear couple is the appropriate response. He further stated however that he believes the prevalence of such hypersensitivity reaction is probably less than 0.5 percent.

A paper was also presented from the Jacobs group on lymphocyte profiling for metal sensitivity in metal-metal hip patients. This paper demonstrated significant reactivity of lymphocytes to  $\text{CoCl}_2$  and nickel in this *in vitro* study. To my memory, this data is similar to that produced by Kathy Merrit some years earlier. However, this paper suggests a greater frequency of reactivity among metal-metal hips when compared with conventional hip arthroplasty. The clinical significance of this finding is completely unknown, as admitted by the presenter.

Other interesting papers demonstrated a general consensus for larger diameter metal-metal bearings to produce decreased wear, particularly when radial clearance is controlled. The issue of carbide content continues to be debated, although there was a slight bias toward high carbide bearings expressed, particularly from the Midland Medical group. No consensus could be reached as to the proper method for monitoring ion levels (serum vs. whole blood versus erythrocytes). Josh Jacobs continues to believe that serum is probably the most reliable way of monitoring levels, and that probably, cobalt levels alone are sufficient to monitor wear. Brodner, from Vienna, Austria, presented what is probably the most comprehensive review of metal ion release. Of note was his report on the failure of cobalt or chromium ions to cross the placental membrane in three women who gave birth in the presence of a metal-metal hip implant.

I believe we need to have a consistent response ready for our sales force and our clients with regard to the hypersensitivity issue. I'm extremely concerned over the medical malpractice potential of this data. I look forward to discussing this with you and your convenience.

Also copied several other abstracts  
of interest - J

